

CLAIMS

- 1 1. A prosthesis, for use within a hollow body structure of a patient, comprising:
 - 2 a coiled body having radially-extending openings formed therethrough, the body
 - 3 movable from a radially-contracted state to a radially-expanded state;
 - 4 a material extending along a coiled path along the entire coiled body; and
 - 5 a dispensable, biologically active agent associated with at least one of the coiled body
 - 6 and the material, said dispensable agent being dispensable into a hollow body structure of a
 - 7 patient.
- 1 2. The prosthesis according to claim 1 further comprising a delay-release material associated
2 with the dispensable agent to delay the release of the dispensable agent into the hollow body
3 structure.
- 1 3. The prosthesis according to claim 2 wherein the delay-release material comprises a
2 biodegradable, delay-release layer.
- 1 4. The prosthesis according to claim 1 wherein the dispensable agent is microencapsulated
2 using a biodegradable encapsulation material so as to delay migration of said drug from said
3 prosthesis.
- 1 5. The prosthesis according to claim 1 further comprising removing a protective layer from
2 said coiled body and material there with so that when removed, said dispensable agent may
3 migrate from said prosthesis.
- 1 6. The prosthesis according to claim 5 wherein the protective layer comprises a
2 biodegradable material so that said protective layer is removed when it biodegrades.
- 1 7. The prosthesis according to claim 5 wherein the protective layer comprises a sheath which
2 can be pulled off the coiled body and material there with to remove the protective layer
3 therefrom.
- 1 8. The prosthesis according to claim 1 wherein said body has longitudinally extending side
2 members and cross members connecting said side members.
- 1 9. The prosthesis according to claim 1 wherein said body is made of metal.

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1 10. The prosthesis according to claim 1 wherein said prosthesis comprises spaced apart turns
2 defining gaps therebetween when in the radially-expanded state.

1 11. The prosthesis according to claim 1 wherein the prosthesis comprises turns, adjacent
2 ones of said turns touching one another when in the radially-expanded state.

1 12. The prosthesis according to claim 1 wherein the material comprises a coiled sleeve of
2 material having inner and outer surfaces, said inner surface defining a sleeve interior
3 containing the entire coiled body.

1 13. The prosthesis according to claim 12 wherein the agent is located at and is dispensable
2 from at least the following location: on the outer surface of the material, the outer surface
3 being placeable against the hollow body structure when the body is in the radially-expanded
4 state so the material may be located at and dispensable from only locations of intimate
5 contact with the hollow body structure.

1 14. The prosthesis according to claim 12 wherein the agent is located at and is dispensable
2 from at least the following location: incorporated into the material to create an agent/material
3 matrix.

1 15. The prosthesis according to claim 12 wherein the agent is located at and is dispensable
2 from at least the following location: on the inner surface of the material.

1 16. The prosthesis according to claim 12 wherein the agent is located at and is dispensable
2 from at least the following location: within the sleeve interior.

1 17. The prosthesis according to claim 1 wherein the material has a radially-inwardly facing
2 inner surface and a radially-outwardly facing outer surface, and material surrounding the
3 body with said inner surface adjacent to the body and the outer surface placeable against the
4 hollow body structure when the body is in the radially-expanded state.

1 18. The prosthesis according to claim 12 wherein the agent is located at and is dispensable
2 from the outer surface of the material so to be located at and dispensable from only locations
3 of intimate contact with the hollow body structure.

1 19. The prosthesis according to claim 1 further comprising first and second dispensable
2 agents.

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- 1 20. The prosthesis according to claim 19 wherein said first agent is layered on top of said
2 second agent.
- 1 21. The prosthesis according to claim 19 wherein said first agent is dispensable prior to the
2 start of dispensing of the second agent.
- 1 22. The prosthesis according to claim 19 wherein at least half of said first agent is
2 dispensable prior to the start of dispensing of the second agent.
- 1 23. The prosthesis according to claim 1 wherein said material is a porous material.
- 1 24. The prosthesis according to claim 23 wherein said porous material comprises porous
2 PTFE.
- 1 25. The prosthesis according to claim 23 wherein said porous material has an inner surface
2 which is substantially impervious to the passage of blood therethrough.
- 1 26. The prosthesis according to claim 1 wherein the dispensable agent is selected from the
2 group comprising: anti-inflammatory drugs, anti-thrombotic/anti-platelet drugs, anti-
3 proliferative drugs, apoptosis-inducing drug, light activated drug, and biological materials.
- 1 27. The prosthesis according to claim 1 wherein the dispensable agent comprises an anti-
2 restenotic agent.
- 1 28. A prosthesis, for use within a hollow body structure of a patient, comprising:
2 a coiled body having radially-extending openings formed therethrough, the body
3 movable from a radially-contracted state to a radially-expanded state;
4 a coiled sleeve of material extending along a coiled path, the material having an inner
5 surface and an outer surface and defining the sleeve interior containing the coiled body; and
6 a dispensable, biologically active agent on said outer surface of the material, said
7 dispensable agent being dispensable into a hollow body structure of a patient.
- 1 29. The prosthesis according to claim 28 wherein the dispensable agent comprises an anti-
2 restenotic agent.
- 1 30. The prosthesis according to claim 28 further comprising a delay-release material
2 associated with the dispensable agent to delay the release of the dispensable agent into the
3 hollow body structure.

1 31. The prosthesis according to claim 28 wherein said prosthesis comprises spaced apart
2 turns defining gaps therebetween when in the radially-expanded state.

1 32. The prosthesis according to claim 28 wherein said material comprises porous PTFE.

1 33. A prosthesis, for use within a hollow body structure of a patient, comprising:
2 a coiled body having radially-extending openings formed therethrough, the body
3 movable from a radially-contracted state to a radially-expanded state;
4 a coiled sleeve of material extending along a coiled path, the material having an inner
5 surface and an outer surface and defining the sleeve interior containing the coiled body; and
6 a dispensable, biologically active agent incorporated into the material to create an
7 agent/material matrix, said dispensable agent being dispensable into a hollow body structure
8 of a patient.

1 34. The prosthesis according to claim 33 wherein the dispensable agent comprises an anti-
2 restenotic agent.

1 35. The prosthesis according to claim 33 further comprising a delay-release material
2 associated with the dispensable agent to delay the release of the dispensable agent into the
3 hollow body structure.

1 36. The prosthesis according to claim 33 wherein said prosthesis comprises spaced apart
2 turns defining gaps therebetween when in the radially-expanded state.

1 37. The prosthesis according to claim 33 wherein said material comprises porous PTFE.

1 38. A prosthesis, for use within a hollow body structure of a patient, comprising:
2 a coiled body having radially-extending openings formed therethrough, the body
3 movable from a radially-contracted state to a radially-expanded state;
4 a coiled sleeve of material extending along a coiled path, the material having an inner
5 surface and an outer surface and defining the sleeve interior containing the coiled body; and
6 a dispensable, biologically active agent on said inner surface of the material or within
7 the sleeve interior, said dispensable agent being dispensable into a hollow body structure of a
8 patient.

1 39. The prosthesis according to claim 38 wherein the dispensable agent comprises an anti-
2 restenotic agent.

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1 40. The prosthesis according to claim 38 further comprising a delay-release material
2 associated with the dispensable agent to delay the release of the dispensable agent into the
3 hollow body structure.

1 41. The prosthesis according to claim 38 wherein said prosthesis comprises spaced apart
2 turns defining gaps therebetween when in the radially-expanded state.

1 42. The prosthesis according to claim 38 wherein said material comprises porous PTFE.

1 43. A method for delivering a biologically active agent to a target site within a hollow body
2 structure of a patient, comprising:

3 delivering a coiled prosthesis to a target site within a hollow body structure of a
4 patient, the prosthesis being in a radially-contracted state, the prosthesis comprising a coiled
5 body having radially-extending openings formed therethrough, a material extending along a
6 coiled path along the entire coiled body, and a dispensable, biologically active agent
7 associated with at least one of the coiled body and the material;

8 radially expanding the prosthesis from the radially-contracted state to a radially-
9 expanded state so to press the prosthesis against a wall of the hollow body structure; and
10 releasing the agent into the hollow body structure.

1 44. The method according to claim 43 further comprising selecting a prosthesis comprising a
2 coiled body having longitudinally extending side members and cross members connecting
3 said side members.

1 45. The method according to claim 43 wherein the radially expanding step is carried out with
2 a prosthesis comprising spaced apart turns defining gaps therebetween when in the radially-
3 expanded state.

1 46. The method according to claim 43 wherein the radially expanding step is carried out with
2 a prosthesis comprising turns which touch one another when in the radially-expanded state.

1 47. The method according to claim 43 further comprising selecting a prosthesis in which the
2 material comprises a coiled sleeve of material, said coiled sleeve of material having inner and
3 outer surfaces, said inner surface defining a sleeve interior containing the entire coiled body.

1 48. The method according to claim 43 further comprising selecting a prosthesis in which the
2 agent comprises first and second dispensable agents.

- 1 49. The method according to claim 48 further comprising selecting a prosthesis having said
2 first agent layered on top of said second agent.
- 1 50. The method according to claim 48 wherein the releasing step is carried out so that at least
2 a portion of said first agent is released prior to the start of release of the second agent.
- 1 51. The method according to claim 48 wherein the controllably releasing step is carried out
2 so that at least half of said first agent is released prior to the start of release of the second
3 agent.
- 1 52. The method according to claim 43 further comprising selecting a prosthesis comprising
2 porous material as said material.
- 1 53. The method according to claim 52 wherein the selecting step is carried out by selecting a
2 prosthesis with said porous material comprising ePTFE.
- 1 54. The method according to claim 52 wherein the selecting step is carried out by selecting a
2 prosthesis with said porous material has a surface which is substantially impervious to the
3 passage of blood therethrough.
- 1 55. The method according to claim 43 further comprising selecting a prosthesis having a
2 delay-release material associated with the dispensable agent.
- 1 56. The method according to claim 55 wherein the selecting step is carried out by selecting a
2 prosthesis in which the delay-release material comprises a biodegradable, delay-release
3 material.
- 1 57. The method according to claim 55 wherein the selecting step is carried out by selecting a
2 prosthesis in which the delay-release material comprises a delay-release layer covering the
3 dispensable agent.
- 1 58. The method according to claim 55 wherein the selecting step is carried out by selecting a
2 prosthesis in which the delay-release material is a component of a matrix of the dispensable
3 agent and the delay-release material.
- 1 59. The method according to claim 55 wherein the selecting step is carried out by selecting a
2 prosthesis in which the delay-release material comprises a biodegradable polymer.

1 60. The method according to claim 55 wherein the delay-release material comprises a
2 protective layer, and further comprising removing the protective layer from the coiled body
3 and material therewith thereby exposing the coiled body and material therewith.

1 61. The method according to claim 43 further comprising selecting a prosthesis comprising a
2 dispensable agent selected from the group comprising: anti-inflammatory drugs, anti-
3 thrombotic/anti-platelet drugs, anti-proliferative drugs, apoptosis-inducing drug, light
4 activated drug, and biological materials.

1 62. The method according to claim 43 further comprising selecting an anti-restenotic agent
2 as the dispensable agent.

1 63. A method for delivering a biologically active agent to a target site within a hollow body
2 structure of a patient, comprising:

3 delivering a coiled prosthesis to a target site within a hollow body structure of a
4 patient, the prosthesis being in a radially-contracted state, the prosthesis comprising a coiled
5 body having radially-extending openings formed therethrough, a coiled sleeve of material
6 extending along a coiled path, the coiled sleeve of material comprising inner and outer
7 surfaces, said inner surface defining a sleeve interior containing the entire coiled body, and a
8 dispensable, biologically active agent on the outer surface of the material;

9 radially expanding the prosthesis from the radially-contracted state to a radially-
10 expanded state so to press the prosthesis against the wall; and

11 releasing the agent from the outer surface of the material and into the hollow body
12 structure.

1 64. The method according to claim 63 further comprising selecting an anti-restenotic agent
2 as the dispensable agent.

1 65. The method according to claim 63 wherein the releasing step comprises temporally
2 controllably releasing the agent into the hollow body structure.

1 66. The method according to claim 63 wherein the radially expanding step is carried out with
2 a prosthesis comprising spaced apart turns defining gaps therebetween when in the radially-
3 expanded state.

1 67. The method according to claim 63 further comprising selecting a prosthesis comprising
2 porous PTFE as said material.

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1 68. A method for delivering a biologically active agent to a target site within a hollow body
2 structure of a patient, comprising:

3 delivering a coiled prosthesis to a target site within a hollow body structure of a
4 patient, the prosthesis being in a radially-contracted state, the prosthesis comprising a coiled
5 body having radially-extending openings formed therethrough, a coiled sleeve of material
6 extending along a coiled path, the coiled sleeve of material comprising inner and outer
7 surfaces, said inner surface defining a sleeve interior containing the entire coiled body, and a
8 dispensable, biologically active agent incorporated into the material to create an
9 agent/material matrix;

10 radially expanding the prosthesis from the radially-contracted state to a radially-
11 expanded state so to press the prosthesis against the wall; and

12 releasing the agent from the agent/material matrix and into the hollow body structure.

1 69. The method according to claim 68 further comprising selecting an anti-restenotic agent
2 as the dispensable agent.

1 70. The method according to claim 68 wherein the releasing step comprises temporally
2 controllably releasing the agent into the hollow body structure.

1 71. The method according to claim 68 wherein the radially expanding step is carried out with
2 a prosthesis comprising spaced apart turns defining gaps therebetween when in the radially-
3 expanded state.

1 72. The method according to claim 68 further comprising selecting a prosthesis comprising
2 porous PTFE as said material.

1 73. The method according to claim 68 further comprising selecting a prosthesis in which the
2 material comprises a coiled sleeve of material, said coiled sleeve of material having inner and
3 outer surfaces, said inner surface opposite said coiled body, said inner surface defining a
4 sleeve interior containing the entire coiled body.

1 74. A method for delivering a biologically active agent to a target site within a hollow body
2 structure of a patient, comprising:

3 delivering a coiled prosthesis to a target site within a hollow body structure of a
4 patient, the prosthesis being in a radially-contracted state, the prosthesis comprising a coiled
5 body having radially-extending openings formed therethrough, a coiled sleeve of material

extending along a coiled path, the coiled sleeve of material comprising inner and outer surfaces, said inner surface defining a sleeve interior containing the entire coiled body, and a dispensable, biologically active agent on the inner surface of the material or within the sleeve interior;

radially expanding the prosthesis from the radially-contracted state to a radially-expanded state so to press the prosthesis against the wall; and

releasing the agent from the inner surface of the material and into the hollow body structure.

75. The method according to claim 74 further comprising selecting an anti-restenotic agent as the dispensable agent.

76. The method according to claim 74 wherein the releasing step comprises temporally controllably releasing the agent into the hollow body structure.

77. The method according to claim 74 wherein the radially expanding step is carried out with a prosthesis comprising spaced apart turns defining gaps therebetween when in the radially-expanded state.

78. The method according to claim 74 further comprising selecting a prosthesis comprising porous PTFE as said material.

79. A method for making a prosthesis for use at a target site within a hollow body structure of a patient comprising:

determining at least one therapy for a patient;

selecting a prosthesis suitable for said at least one therapy, said prosthesis comprising a coiled body having radially-extending openings formed therethrough, a material extending along a coiled path along the entire coiled body, and first and second dispensable, biologically active agents for said therapy, said first and second agents being associated with at least one of said coiled body and said material; and

said selecting step being carried out so that at least some of said first agent is releasable at a target site within a hollow body structure of a patient prior to the start of the release of the second agent at the target site.

80. The method according to claim 79 wherein the selecting step is carried out by selecting a prosthesis with a porous material as said material.

- 1 81. The method according to claim 80 wherein the selecting step is carried out with the
2 porous material comprising ePTFE.
- 1 82. The method according to claim 80 wherein the selecting step is carried out by selecting a
2 prosthesis with said porous material having a surface which is substantially impervious to the
3 passage of blood therethrough.
- 1 83. The method according to claim 79 wherein the selecting step is carried out by selecting a
2 prosthesis having said first agent layered on top of said second agent.
- 1 84. The method according to claim 79 wherein said selecting step is carried out so that
2 said first agent is releasable over a first period and said second agent is releasable over a
3 second period, said first and second periods at least partially overlapping.
- 1 85. The method according to claim 79 wherein the selecting step is carried out by selecting a
2 prosthesis having a delay-release material associated with at least one of the first and second
3 agents.
- 1 86. The method according to claim 85 wherein the selecting step is carried out by selecting a
2 prosthesis in which the delay-release material comprises a biodegradable, delay-release layer.
- 1 87. The method according to claim 79 wherein the selecting step comprises selecting a
2 prosthesis comprising dispensable agents selected from the group comprising: anti-
3 inflammatory drugs, anti-thrombotic/anti-platelet drugs, anti-proliferative drugs, apoptosis-
4 inducing drug, light activated drug, and biological materials.
- 1 88. The method according to claim 79 further comprising selecting anti-restenotic agents as
2 the dispensable agents.
- 1 89. The method according to claim 79 wherein the selecting step comprises selecting a
2 prosthesis in which the material comprises a coiled sleeve of material, said coiled sleeve of
3 material having inner and outer surfaces, said inner surface defining a sleeve interior
4 containing the entire coiled body, the selecting step being carried out with the agents being
5 releasable from at least one of the following locations: the outer surface of the material,
6 incorporated into the material to create an agent/material matrix, on the inner surface of the
7 material, and within the sleeve interior.

1 90. The method according to claim 79 wherein the selecting step comprises selecting a
2 prosthesis comprising spaced apart turns defining gaps therebetween when in the radially-
3 expanded state.

1 91. A method for making a prosthesis for use at a target site within a hollow body structure
2 of a patient comprising:

3 placing a length of a material in contact with a mixture of a carrier and a dispensable,
4 biologically active agent;

5 removing at least a substantial portion of the carrier from the mixture leaving said
6 agent in contact with the material to create an agent-laden material;

7 combining the agent-laden material with a radially-expandable stent to create a
8 prosthesis suitable for use within a hollow body structure of a patient.

1 92. The method according to claim 91 wherein the placing step is carried out using a porous
2 material as the material.

1 93. The method according to claim 92 wherein the placing step is carried out with the porous
2 material comprising ePTFE.

1 94. The method according to claim 92 further comprising selecting a length of porous sleeve
2 material as said porous material, said porous sleeve material comprising inner and outer
3 surfaces, said inner surface defining a sleeve interior containing the entire stent following the
4 combining step.

1 95. The method according to claim 94 wherein said placing step is carried out by placing
2 said mixture into said sleeve interior.

1 96. The method according to claim 95 wherein the selecting step is carried out using a sleeve
2 material having open ends, and the placing step comprises at least temporarily sealing one
3 said open end.

1 97. The method according to claim 91 wherein said removing step is carried out by draining
2 away excess amounts of said mixture and then at least partially drying said length of material.

1 98. The method according to claim 91 further comprising selecting an agent from the group
2 comprising: anti-inflammatory drugs, anti-thrombotic/anti-platelet drugs, anti-proliferative
3 drugs, apoptosis-inducing drug, light activated drug, and biological materials.

1 99. The method according to claim 91 further comprising selecting an anti-restenotic agent
2 as the biologically active agent.

1 100. The method according to claim 91 wherein the combining step is carried out with a
2 prosthesis comprising spaced apart turns defining gaps therebetween when in the radially-
3 expanded state.

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